

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

September 10, 2001

Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD

9:00 – 1:00	First PMA Discussion, Recommendations, and Voting	
9:00 a.m.	Call to Order	Cynthia Tracy, M.D., Chairperson
9:05 – 9:15 a.m.*	Open Public Hearing*	
9:15 – 10:15 a.m.	Sponsor Presentation: AGA Medical P000039, Amplatzer® Septal Occluder and Delivery System Franck Gougeon, Executive Vice President, AGA Medical Corporation Ziyad Hijazi, MD, University of Chicago Children's Hospital, Chicago John Cheatham, MD, The Nemours Cardiac Center, Orlando John Moore, MD, St. Christopher's Children's Hospital, Philadelphia	
10:15 – 10:30 a.m.	FDA Presentation Donna Buckley, lead reviewer John E. Stuhlmuller, MD, clinical reviewer	
10:30 – 12:45 p.m.	Open Committee Discussion, Recommendations, and Voting	Cynthia Tracy, M.D.
11:00 – 11:15 a.m.	Break	
12:45 – 1:00 p.m.*	Open Public Hearing*	
1:00 p.m.	Adjourn – Break for Lunch	

2:00 – 6:00 p.m.	Second PMA Discussion, Recommendations, and Voting	
2:00 p.m.	Call to Order	Cynthia Tracy, M.D.
2:05 – 2:15 p.m.*	Open Public Hearing*	
2:15 – 3:15 p.m.	Sponsor Presentation: NMT Medical, Inc. P000049, CardioSEAL Septal Occlusion System with Qwikload John Ahern, President, CEO and Chairman, NMT Medical, Inc Carol Ryan, Vice President, Research and Development, NMT Medical John E. Mayer, MD, Boston Children’s Hospital / Harvard Medical School Peter C. Laussen, MBBS, Boston Children’s Hospital / Harvard Medical School Kathy J. Jenkins, MD, MPH, Boston Children’s Hospital / Harvard Medical School Kimberlee Gauvreau, ScD, Boston Children’s Hospital / Harvard Medical School	
3:15 – 3:30 p.m.	FDA Presentation Donna Buckley, lead reviewer John E. Stuhlmuller, clinical reviewer	
3:30 – 5:45 p.m.	Open Committee Discussion, Recommendations, and Voting	Cynthia Tracy, M.D.
4:00 – 4:15 p.m.	Break	
5:45 – 6:00 p.m.*	Open Public Hearing*	
6:00 p.m.	Adjourn	

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Tracy will recognize unscheduled speakers as time allows.

There were no requests to speak during the Open Public Hearings on September 10. Megan Moynahan will summarize for the record several letters received on the topic of septal occluders.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.